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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,020	04/27/2001	Douglas A. Treco	50010/017003	1549
35093	7590	09/08/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			VOGEL, NANCY S	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 09/08/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

GM

**Office Action Summary**

Application No.

09/845,020

Applicant(s)

TRECO ET AL.

Examiner

Nancy T. Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-50 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 35-50 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 3/30/04.  
 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) ☐ Notice of Informal Patent Application (PTO-152)  
 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 35-50 are pending in the case.

Receipt of the Reply to the Office action on 3/22/04, an Information disclosure statement on 3/30/04, and five references on 5/27/04, is acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action

### ***Claim Rejections - 35 USC § 112***

Claims 35-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 9/23/03. Applicant's arguments, submitted 3/22/04, have been considered but have not been found convincing.

Applicant has argued that the specification provides an enabling disclosure for the use of cells in which G-CSF expression has been activated in therapeutic in vivo methods of treatment. Applicant cites WO 93/09222 and Roth et al., (which have been considered only as evidence in support of applicant's response to patentability issues raised in the previous Office action) in support of the argument. Applicant argues that

these references, which disclose examples of the production of human growth hormone and erythropoietin in mice implanted with cells producing these compounds, and an example of introduction of cells modified to express Factor VIII into patients suffering from hemophilia "clearly establish that cells that have been engineered to express a therapeutic protein... can be implanted into an animal (e.g. a human) to produce the protein in the animal". Applicant further argues that these examples show that "expression using the ex vivo gene therapy approaches used in the present invention can be used to achieve long lasting, constant expression, if desired", and further argues that those of skill in the art "certainly could select a particular cell type to use and test it for expression levels".

However, it is maintained that the citation of examples of delivery of different gene products, using different cell expression systems, does not provide adequate evidence that the instant claims, which recite a method of delivery of G-CSF to an animal which may be human via an ex vivo gene therapy technique, are enabled by the instant specification. It is considered that each therapeutic protein differs in such properties as production amount, levels of secretion, stability, immunogenicity, etc. The fact that others in the art have succeeded in the implantation of particular cells expressing a particular gene product in particular animals, at particular locations and at particular dosages, does not remedy the lack of enablement for the methods of the instant application. The instant specification provides only speculative guidance for the implantation of cells expressing the G-CSF gene, in animals so that the G-CSF is

successfully delivered, which is not considered to be sufficient for this unpredictable area of research. Therefore, the rejection is maintained.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

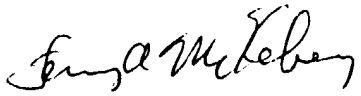
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
TERRY MCKELVEY  
PRIMARY EXAMINER